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REMARKS

Claims 1, 8-11, 13-24, 32-45 and 48-56 are pending in the application. Claims 2-7, 12, 25-31, 46, 47, 57 and 58 have been withdrawn from consideration by the Examiner as being non-elected. Claims 48-52 have been canceled, without prejudice to filing one or more divisional applications directed to the canceled subject matter thereof.

At page 3 of the Office Action, claims 1, 8-11, 13-24 and 32-33 have been rejected under 35 U.S.C. § 112, first paragraph because of lack of enablement. For brevity, reference is made to page 3 of the Office Action for the complete reasons for rejection.

While Applicants respectfully disagree with and traverse this rejection, claims 1, 24, 32 and 33 have been amended to remove the phrase "or prevention" to expedite allowance of the present application, without prejudice to filing of one or more divisional patent applications directed to the canceled subject matter thereof.

Accordingly, Applicants respectfully request that the rejection of claims 1, 8-11, 13-24 and 32-33 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

At page 4 of the Office Action, claims 49-52 have been rejected under the judicially-created doctrine of obviousness-type double patenting. For brevity, reference is made to page 4 of the Office Action for the complete reasons for rejection.

Since claims 49-52 have been canceled without prejudice, Applicants respectfully request that the rejection be reconsidered and withdrawn.

At pages 4-5 of the Office Action, claims 48-52 and 56 have been rejected under 35 U.S.C. §102(b) as anticipated by US 5,767,115 ("115 patent") or US 5,846,966 ("966 Patent"). For brevity, the reasons for rejection are not repeated herein but reference is made to the outstanding Office Action.

Applicants respectfully traverse this rejection and request that the rejection be reconsidered and withdrawn.

Claims 48-52 have been canceled, without prejudice to filing one or more divisional applications directed to the canceled subject matter thereof. Therefore, the rejection of claims 48-52 is moot and should be withdrawn.

Regarding the rejection of claim 56, claim 56 reads as follows:

"A method of reducing plasma or tissue concentration of at least one compound selected from the group consisting of phytosterols, 5 α -stanols and mixtures thereof, comprising administering to a mammal in need of such treatment an effective amount of at least one sterol absorption inhibitor or a prodrug or a pharmaceutically acceptable salt thereof and at least one bile acid sequestrant".

In order to support an anticipation rejection under §102(b), each and every element of the claimed invention or its substantial equivalent must be found within the four corners of a single reference cited by the Examiner to anticipate.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Claim 56 does not refer to atherosclerosis. Neither the '115 patent nor the '966 patent disclose reduction of plasma or tissue concentration of phytosterols, 5 α -stanols or mixtures thereof. Therefore, Applicants respectfully request that the rejection of claim 56 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

At pages 5-8 of the Office Action, claims 1, 8-11, 13-24, 32-42 and 53-55 have been rejected under 35 U.S.C. §103(a) as obvious over US 5,846,966 ("Rosenblum et al.") in view of Berge et al. (Science, 2000; 290:1771-75).

For brevity, the reasons for rejection are not repeated herein but reference is made to the outstanding Office Action.

In response, Applicant is submitting herewith a Declaration Of Harry Davis, Jr., Ph.D. under 37 C.F.R. § 1.131 proving a date of invention prior to December 1, 2000, which is the publication date of the Berge et al. reference. The cited Berge et al. is no longer available as a reference, so the art-related rejections should be withdrawn. Accordingly, reconsideration and withdrawal of the §103(a) rejection is respectfully requested.

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Applicant respectfully requests that the Examiner return an initialed PTO-1449 form for the Information Disclosure Statement submitted herewith and each of the Information Disclosure Statements submitted on October 28, 2003 and November 26, 2003, indicating that the Examiner has considered each of the references cited therein.

In view of the foregoing remarks, it is respectfully submitted that all of the pending claims in the present application comply with the requirements of 35 U.S.C. § 112 and are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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